-20-

## **CLAIMS**

5

Į0

- 1. A method for an early diagnosis of cancer in a subject comprising the steps:
  - i) providing a fecal sample from said subject;
  - ii) treating said sample to obtain a feecs-derived microorganism sample;
  - iii) identifying in the microorganism sample one or more types of microorganisms contained therein; and
- iv) determining for each of said microorganisms its relative fraction from the total count of microorganisms in said sample, the relative fractions being indicative of the presence or absence of cancer in said subject.
- 2. The method of claim 1, wherein said subject is a human subject.
- 3. The method of Claim 1, wherein said microorganisms are isolated by colonies formation on selective culture mediums.
- 15 4. The method of Claim 1, wherein said relative fraction of each of said microorganisms is determined by calculating the percentage of said microorganism from the total count of microorganisms in the same or corresponding sample.
  - 5. The method of Claim 1, wherein said microorganisms are bacteria.
- 20 6. The method of Claim 5, wherein said bacteria are Gram-negative anaerobic bacteria.
- 7. The method of Claim 6, wherein said Gram-negative anaerobic bacteria is of a genus selected from the group consisting of Escherichia, Salmonella, Shigella, Klebsiella, Yersinisa, Enterobacter, Hemophilus, Gardnerella and Pasteurella
  - 8. The method of Claim 7, wherein said bacteria is E.coli.
  - 9. The method of Claim 8, wherein E.coli coliform is isolated from said fecal sample by culturing the feces-derived sample of bacteria on a culture medium

2 1g F

20

25

selective for E.coli.

- 10. The method of Claim 9, wherein the culture medium is selected from the group consisting of MacConkey agar and m-Endo agar
- 11. The method of Claim 5, wherein said bacteria are Gram-positive bacteria.
- 5 12. The method of Claim 11, wherein said Gram-positive bacteria is of a genus selected from the group consisting of Staphylococcus, Enterococcus, Streptococcus, Lactococcus.
  - 13. The method of Claim 12, wherein said bacteria is Streptococcus bovis and/or Enterococcus sp.
- 14. The method of Claim 13, wherein Enterococci coliform is isolated from said fecal sample by culturing the feces-derived sample of bacteria on a culture medium selective for Enterococcus.
  - 15. The method of Claim 14, wherein said culture medium is selected from the group consisting of Slanetz-Bartley agar and Bile-esculine-azide agar.
- 16. A method for an early diagnosis of cancer in a subject comprising the steps:
  - i) providing a fecal sample from said subject;
  - ii) treating said focal sample to obtain a feces-derived bacteria sample therefrom;
  - iii) identifying in the bacteria sample one or more types of microorganisms; and
  - iv) determining for each of said microorganisms its relative fraction from the total count of microorganisms in said sample or in a corresponding sample;
  - v) isolating one or more microorganisms from said sample for which their relative fraction was determined;
  - vi) preparing a diagnostic sample containing one or more of the isolated microorganisms, the fraction of the microorganisms in said diagnostic sample corresponds to the relative fraction thereof in the fecal sample, as determined in step (iv); and

- vii) interacting said diagnostic sample with cancer cells for a time period sufficient to detect lysis of said cancer cells by said diagnostic sample, thereby determining for said fecal sample a tumor cell necrosis index (TCNI).
- 5 17. The method of Claim 16, wherein said feeal sample is a human feeal sample.
  - 18. The method of Claim 17, wherein said treatment includes removal of undesired contamination from said fecal sample to obtain an uncontaminated feces-derived bacteria sample.
- 10 19. The method of Claim 16, wherein said microorganisms are isolated by colonies formation on selective culture mediums.
- 20. The method of Claim 16, wherein said relative fraction of each of said microorganisms is determined by calculating the percentage of said microorganism from the total count of microorganisms in the same bacteria
  15 sample.
  - 21. The method of Claim 16, wherein said microorganisms are bacteria.
  - 22. The method of Claim 21, wherein said bacteria are Gram-negative anaerobic bacteria.
- 23. The method of Claim 22, wherein said Gram-negative anaerobic bacteria is of a genus selected from the group consisting of Escherichia, Salmonella, Shigella, Klehsiella, Yersinisa, Enterobacter, Hemophilus, Gardnerella and Pasteurella
  - 24. The method of Claim 23, wherein said bacteria is E.coli.
- 25. The method of Claim 24, wherein E.coli coliform is isolated from said
  25 fecal sample by culturing the feces-derived sample of bacteria on a culture
  medium selective for E.coli.
  - 26. The method of Claim 25, wherein the culture medium is selected from the group consisting of MacConkey agar and m-Endo agar.
  - 27. The method of Claim 21, wherein said bacteria are Gram-positive bacteria.

- 28. The method of Claim 27, wherein said Gram-positive bacteria is of a genus selected from the group consisting of *Staphylococcus*, *Enterococcus*, *Streptococcus*, *Lactococcus*.
- 29. The method of Claim 29, wherein said bacteria is Streptococcus bovis and/or Enterococcus sp.
  - 30. The method of Claim 29, wherein Enterococci coliform is isolated from said fecal sample by culturing the feces-derived sample of bacteria on a culture medium selective for Enterococcus.
- 31. The method of Claim 30, wherein said culture medium is selected from the group consisting of Slanetz-Bartley agar and Bile-esculine-azide agar.
  - 32. The method of Claim 16, wherein said cancer cells are a standard culture of cancer cells.
  - 33. The method of Claim 32, wherein said standard culture of cancer cells having the accession No. ATCC MCF7.
- 15 34. The method of Claim 16, wherein said mixture is interacted with the cancer cells for a time period sufficient to determine the extent of interaction between the bacteria and the cancer cells.
- 35. The method of Claim 34, wherein the number of interacted and/or non-interacted cancer cells present at the end of said time period is determined, based on which a number cell necrosis index (TCNI) is calculated.
  - 36. A method for an early diagnosis of cancer in a subject comprising the steps:
    - i) providing a fecal sample from said subject;
    - ii) treating said sample to obtain a feces-derived microorganism sample;
- 25 iii) identifying in the microorganism sample at least one type of microorganism capable of expressing in a healthy subject L-asparaginase II (L-PAR II); and
  - iv) determining level of expression of L-PAR II or level of activity of L-PAR II, said level is indicative of the presence or absence of cancer cells

in said subject.

- 37. The method of Claim 36, wherein said fecal sample is a human fecal sample.
- 38. The method of Claim 36, wherein said treatment includes removal of undesired contamination from said feeal sample to obtain an uncontaminated feces-derived bacteria sample.
  - 39. The method of Claim 36, wherein said microorganisms are isolated from the seces-derived bacteria sample by colonies formation on selective culture plates.
- 10 40. The method of Claim 36, wherein said microorganism capable of expressing I-PAR II is E. coli.
  - 41. The method of Claim 36, wherein low levels of expression of L-PAR II or of activity of L-PAR II, indicate the presence of cancer cells in said subject.